

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte MONTY KRIEGER, SUSAN L. ACTON and ATTILIO RIGOTTI

MAILED

Appeal No. 2001-1495  
Application No. 08/765,108<sup>1</sup>

SEP 25 2001

HEARD: August 16, 2001

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

Before WILLIAM F. SMITH, SCHEINER and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

REMAND TO THE EXAMINER

On consideration of the record we find this case is not in condition for a decision on appeal. For the reasons that follow, we remand the application to the examiner to consider the following issues and to take appropriate action.

<sup>1</sup> We note appellants' statement (Brief, page 2) that the instant application on appeal is related to Application No. 08/265,428. An appeal (1997-3321) of Application No. 08/265,428 is currently pending. Accordingly, we have considered these two appeals together.

Claims 11, 44, 48, 49 and 50 are illustrative of the subject matter on appeal and are reproduced below:

11. An isolated nucleic acid molecule encoding a scavenger receptor protein type BI which selectively binds to low density lipoprotein and to modified lipoprotein having the characteristics of acetylated low density lipoprotein, which hybridizes to SEQ ID Nos. 3 and 7.
44. A method for screening for a compound which alters the binding of scavenger receptor protein type BI, which is encoded by a nucleotide molecule hybridizing to SEQ ID Nos. 3 and 7 and which selectively binds to low density lipoprotein and to modified lipoprotein having the characteristics of acetylated low density lipoprotein, comprising  
  
    providing reagents for use in an assay for binding of low density lipoprotein or modified low density lipoprotein to the scavenger receptor protein,  
  
    adding the compound to be tested to the assay, and  
  
    determining if the amount of modified low density lipoprotein or low density lipoprotein which is bound to the scavenger receptor protein is altered as compared to binding in the absence of the compound to be tested.
48. A method for removing low density lipoprotein from patient blood comprising reacting the blood with immobilized scavenger receptor protein type B, wherein the scavenger receptor protein type BI is encoded by a nucleotide molecule hybridizing to SEQ ID Nos. 3 and 7 and selectively binds to low density lipoprotein and to modified lipoprotein having the characteristics of acetylated low density lipoprotein, under conditions wherein the low density lipoprotein is bound to the scavenger receptor.
49. A method for inhibiting uptake of lipoprotein or lipids by adipocytes comprising selectively inhibiting binding of lipoprotein to the scavenger receptor protein type BI, wherein the scavenger receptor protein type BI is encoded by a nucleotide molecule hybridizing to SEQ ID Nos. 3 and 7 and selectively binds to low density lipoprotein and to modified lipoprotein having the characteristics of acetylated low density lipoprotein under conditions wherein the low density lipoprotein is bound to the scavenger receptor.

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50. A method for screening patients for abnormal scavenger receptor protein activity or function comprising
- determining the presence of scavenger receptor protein type BI, wherein the scavenger receptor protein type BI is encoded by a nucleotide molecule hybridizing to SEQ ID Nos. 3 and 7 and selectively binds to low density lipoprotein and to modified lipoprotein having the characteristics of acetylated low density lipoprotein, and
  - determining if the quantity present or the function of the receptor is equivalent to that present in normal cells.

The reference relied upon by the examiner is:

Calvo et al. (Calvo), "Identification, Primary Structure, and Distribution of CLA-1, a Novel Member of the CD36/LIMPIII Gene Family," J. Biol. Chem., Vol. 268, No. 25, pp. 18929-18935 (1993)

#### GROUND OF REJECTION

Claims 11-13, 19-22 and 44-50 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to enable the production of an isolated nucleic acid encoding a scavenger receptor protein lacking one of the amino acid sequences that are disclosed in SEQ ID Nos: 4, 6 and 8 of the instant invention.

Claim 19 stands rejected under 35 U.S.C. § 112, first paragraph, as the specification that fails to adequately describe the claimed invention.

Claim 49 stands rejected under 35 U.S.C. § 112, first paragraph, as the specification that fails to adequately describe the claimed invention in such a way as to enable one skilled in the art to make and/or use the invention.

Claims 44-50 stand rejected under 35 U.S.C. § 112, first paragraph, because they are incomplete in failing to recite sufficient elements to provide the claimed method.

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Claims 11-15, 19-22 and 44-50 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the phrase "scavenger receptor protein type BI"

Claims 11-12, 15, 19-22 and 44-50 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the term "hybridizing."

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the phrase "or a degenerate variant thereof."

Claim 21 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite because the physical relationship between the "molecule of claim 11" and the "expression vector" is not recited.

Claim 22 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite because the physical relationship between the "composition of claim 21" and the "host cell" is not recited.

Claim 46 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the phrase "naturally occurring or synthetic compounds."

Claim 11, 19 and 20 stand rejected under 35 U.S.C. 102(a) as anticipated by Calvo.

Claims 21 and 22 stand rejected under 35 U.S.C. § 103 as being unpatentable over Calvo.

We remand.

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### DISCUSSION

Initially we note that the Answer contains the signatures of two conferees, in addition to the signature of the examiner, suggesting that an Appeal Conference was held. See MPEP § 1208. Nevertheless, the briefings presented to the Board by both appellants, and the examiner, do not allow this Merits Panel to perform a reasoned review of either parties position. Accordingly, we remand the application to the examiner to consider the following issues and take appropriate action.

1. Improper Examiner's Answer:

In setting forth the rejections in the Answer<sup>2</sup>, the examiner refers to Paper Numbers 7 and 10. See e.g., Answer, pages 13 and 15. This is improper.

In relevant part, the Manual of Patent Examining Procedure (MPEP) § 1208 (6<sup>th</sup> ed., July 1996), states "[a]n examiner's answer should not refer, either directly or indirectly, to more than one prior Office action."

2. Inventorship:

We note appellants' statement (Brief<sup>3</sup>, page 2) "that the inventorship of this application was amended in the Preliminary Amendment mailed December 23, 1996 (Paper No. 6), canceling claims 1-8 and 23-43, since Attilio Rigotti is

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<sup>2</sup> Paper No. 22, mailed March 26, 1997.

<sup>3</sup> Paper No. 18, received February 18, 1999.

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not an inventor of the remaining claims." It does not appear, on this record, that the examiner acknowledged this change of inventorship.

In addition, we note appellants' reliance (see e.g., Brief, page 48) on the Declaration filed under 37 C.F.R. § 1.131. We note appellants' Declaration lists the "[a]pplicants" as Monty Krieger, Susan L. Acton, and Alan M. Pearson. However, Monty Krieger and Susan L. Acton are the only declarants. The record is unclear with regard to the contribution made by Alan M. Pearson.

Upon return of this application to the examiner, these inventorship issues should be clarified.

3. Unclear statement of the claims under rejection:

First, we note that the examiner withdrew (Answer, page 15) claim 15 from the rejection of claims 11-13, 17, 19-22 and 44-50 under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to enable the production of an isolated nucleic acid encoding a scavenger receptor protein lacking one of the amino acid sequences that are disclosed in SEQ ID Nos: 4, 6 and 8 of the instant invention. The examiner's statement of this rejection (Answer, page 3), however, includes claim 17. According to appellants (Brief, page 2) "[c]laims 16-18 were cancelled...." The examiner finds (Answer, page 2) appellants' "statement of the status of the claims contained in the brief is correct." Therefore the inclusion of claim 17 in the examiner's statement of the rejection appears to be in error.

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Second, with regard to the rejection of claims 11, 19 and 20 under 35 U.S.C. 102(a) as anticipated by Calvo, we note the examiner's statement (Answer, page 13) that the Final:

rejection is being withdrawn as applied to claim 12. Claim 12 was originally interpreted as reciting those cell types in which SR-BI/CLA-1 protein was naturally expressed, however, it is apparent from [a]ppellant's arguments that the cells recited in claim 12 are intended to be recombinant cells which contain a heterologous nucleic acid encoding a SR-BI/CLA-1 protein. Such cells were not disclosed or suggested by Calvo et al.

Claim 15, however, was also included under this same ground of rejection in the Final rejection, but is not included in the examiner's statement of this rejection in the Answer. See Answer, page 12. The examiner offers no comment, on this record, as to why claim 15 was excluded from this rejection in the Answer. Therefore, it is unclear if the examiner made a typographical error, or if the examiner intended to remove claim 15 from this rejection.

Finally, the Final rejection under 35 U.S.C. § 103 over Calvo, included claims 13, 14 and 19. However, these claims are not presented in the statement of the rejection in the Answer (see page 13). According to the examiner (Answer, page 14):

Claims 13 and 14 were inadvertently included in this rejection when it was restated in [the Final rejection] section 9 of Paper Number 10. However, as stated therein, "[a]pplicant has antedated the Calvo et al. publication in so far as it is applicable to an isolated nucleic acid encoding a hamster CLA-1 protein by showing the isolation of a cDNA encoding hamster CLA-1 (a.k.a. BI) prior to the publication of the Calvo et al. publication". Since claim 14 is limited to an isolated nucleic acid encoding the amino acid sequence presented in SEQ ID NO:4 of the instant application, which is the hamster protein relied upon in the declaration to antedate the Calvo

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et al. publication, it is clear from the record that this rejection was no longer applicable to claim 14."

In contrast to the examiner's statement (id.) that "claim 14 is limited to an isolated nucleic acid encoding the amino acid sequence presented in SEQ ID NO:4 ...", we find no such limitation in claim 14. Claim 15 is the only claim on appeal that makes reference to SEQ ID NO:4. Therefore, the examiner's position is unclear.

In addition, the examiner makes no statement as to why claim 19 was removed from this rejection. It does not appear that the examiner's rationale (id.) regarding the hamster sequence, applies to claim 19, drawn to a human scavenger receptor. Accordingly, it is unclear if the examiner made a typographical error, or if the examiner intended to remove claim 19 from this rejection.

Upon return of this application to the examiner, the record should be reviewed to insure the claims are properly set forth for each ground of rejection.

4. Both the examiner and appellants fail to address all the issues under 35 U.S.C. § 112, second paragraph:

The Final Rejection sets forth six rejections under 112, second paragraph. While appellants recognize (Brief, page 40) each ground of rejection under 35 U.S.C. § 112, second paragraph, appellants' Brief, addresses (see Brief, pages 41-42) only three of these rejections. As set forth in 37 C.F.R. § 1.192(c)(8) (1996) "[t]he brief shall contain ... [t]he contentions of appellant with respect to each of the issues presented for review...."

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As set forth in 37 C.F.R. § 1.192(d) (1996) "[i]f a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and provided with a period of one month within which to file an amended brief...." We note the examiner did not notify appellants of the defective Brief, nor does the Answer respond in any way to appellants' arguments or the absence of an argument with regard to the rejections under 35 U.S.C. § 112, second paragraph.

We note appellants' Reply Brief, attempts to correct, at least in part, the deficiency in their Brief. See Reply Brief, pages 11-13. We note, however, appellants' comment (Reply Brief, page 13) that "[t]he remaining rejections seem to go to particular preferences by the [e]xaminer which [a]ppellant would certainly make if required but for the status of the prosecution and the other rejections." We note the examiner entered the Reply Brief, without comment. See Paper No. 24, mailed August 10, 1999.

We remind both the examiner and appellants that analyzing claims based on "speculation as to meaning of the terms employed and assumptions as to the scope of such claims" is legal error. In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962). In this regard, we would urge appellants and the examiner to work together to determine the appropriate interpretation of the claims.

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5. The examiner failed to respond to appellants' arguments regarding the rejection of claim 49 under 35 U.S.C. § 112, first paragraph:

According to the examiner (Answer, page 8) claim 49 contains "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." In response, appellants provide a number of arguments (see Brief, pages 37-39) including citations to the specification, where support can be found for the claimed invention.

The examiner provides no response to appellants' arguments in the "Response to Argument" section of the Answer. The only statement made by the examiner regarding this particular rejection, is in the context of the statement of the rejection. Therein the examiner merely states (Answer, page 8) "[a]ppellant's [sic] traversal of this rejection as 'nothing more than a rejection for lack of utility under 35 U.S.C. 101' is wholly inapplicable to this rejection." This, however, does not explain why the examiner believes those sections of the specification, relied upon by appellants in their arguments, are insufficient to support the claimed invention.

Upon return of this application, the examiner should take the opportunity to address appellants' arguments, including, an explanation as to why the examiner believes those sections of the specification relied upon by appellants are insufficient to enable the claimed invention.

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6. The rejection of claims 44-50 under 35 U.S.C. § 112, first paragraph:

According to the examiner (Answer, page 9) "[e]ach of ... claims [44-50] is drawn to a method and yet none of them recite sufficient elements to provide the claimed method." By way of example, the examiner finds (id.) "[c]laim 44... includes the step of 'providing reagents for use in an assay for binding' which still lacks any defining elements."

In response appellants address only claim 50. See Brief, page 40. Appellants do not discuss claims 44-49 which are also included in this rejection. The examiner, however, fails to respond to appellants' argument with regard to claim 50, or the absence of argument with regard to claims 44-49.

Upon return of this application, the examiner should address appellants' argument, or lack of argument, with regard to each claim under rejection.

7. The Reply Brief addresses phantom rejections under 35 U.S.C. § 112, second paragraph:

In a section entitled "[t]he [c]laims are definite under 35 U.S.C. § 112, second paragraph" appellants' argue (Reply Brief, page 11) that the rejection of the claims "on the basis that the claims fail to define method steps ... ignores the claim language." In this regard, appellants provide (id.) a quote from "page 8 of the [e]xaminer's Answer...."

We note that the rejection from which appellants quote (see Answer, page 8) is a rejection of claim 49 under 35 U.S.C. § 112, first paragraph. Similarly, the issue of "method steps" is from a rejection of claims 44-50 under 35 U.S.C. § 112, first paragraph. See Answer, page 9.

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Given the rejections at issues are under 35 U.S.C. § 112, first paragraph, and not the second paragraph of this section, appellants' statement (Reply Brief, page 12) that "[t]here is some additional argument by the [e]xaminer regarding enablement of the claimed methods for therapeutic applications which, to the extent it is relevant, is addressed more properly above under the first paragraph rejection, not definiteness" is unclear.

Appellants should take this opportunity, to clarify their position on this record.

8. The rejection under 35 U.S.C. § 102:

The sole issue presented for review, is whether the declaration of Monty Krieger and Susan L. Acton is sufficient to antedate the Calvo reference. However, as discussed above, the inventorship of the claimed invention is less than clear. Accordingly, we are unable to address the merits of this rejection until the inventorship issue is resolved.

In addition, we note that appellants rely (Brief, pages 42-50) on their declaration demonstrating the cloning and expression of hamster protein, and hybridization of hamster nucleic acid to the mouse gene, in an attempt to antedate the Calvo reference relied upon by the examiner. We further note that appellants admit (Declaration<sup>4</sup>, paragraph 2) that the gene isolated by Calvo encodes the human homologue of the hamster class B1 scavenger receptor protein. If prosecution is resumed, appellants should take the opportunity to

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<sup>4</sup> Paper No. 9, received January 5, 1998.

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discuss their position in view of In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993) and In re Deuel, 51 F.3d 1552, 34 USPQ 1210 (Fed. Cir. 1995). As set forth in Deuel, 51 F.3d at 1559, 34 USPQ at 1215 “[w]e today reaffirm the principle, stated in Bell, that the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious....”

9. The rejection under 35 U.S.C. § 103:

Appellants’ respond to the rejection of claims 21 and 22 under 35 U.S.C. § 103 as obvious over Calvo at pages 51-56 of the Brief. The examiner, however, fails to respond to appellants’ arguments.

In addition, we note that Calvo teach (page 18934, bridging sentence, columns 1 and 2) that “[s]o far it is difficult to envisage a function for CLA-1, but if its location on the plasma membrane is confirmed, one could speculate on the basis of its structural homology to CD36 that CLA-1 could act as a receptor for extracellular products” [emphasis added]. In this regard, we remind the examiner, if the prior art does not teach any specific or significant utility for the disclosed compounds, then the prior art is not sufficient to render structurally similar claims prima facie obvious because there is no motivation for one of ordinary skill in the art to make the reference compounds, much less any structurally related compounds. In re Sterniski, 444 F.2d 581, 586, 170 USPQ 343, 348 (CCPA 1971).

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Upon return of this application, the examiner should step back and review this record, including the cited prior art, and appellants' arguments. If, after having an opportunity to review this record, the examiner believes that this rejection should be maintained, the examiner should clearly explain why appellants' arguments are not persuasive. In addition, the examiner should explain why this rejection should be maintained in view of Stemniski.

#### OTHER ISSUES

While we take no position on the merits of any rejection on appeal, in the interest of judicial economy, we make the following observations based on our understanding of the claims and the briefings of both the examiner and appellants.

1. The Information Disclosure Statement (IDS) received May 4, 1998:

The IDS received May 4, 1998 (Paper No. 11) was not considered. In addition, there is no explanation on this record as to why this IDS was not considered.

2. United States Patent No. 5,998,141 ('141):

The '141 patent discloses (Column 6, lines 1-20)

The nucleotide sequence of the human SR-BI cDNA, shown in ... SEQ ID NO. 1 encodes a protein of 509 amino acids. SEQ ID NO. 1 contains the nucleotide sequence of the cDNA disclosed in Calvo and Vega (1993) J. Biol. Chem. 268:18929, and contains in addition a complete 5' end. The amino acid sequence of the protein set forth in SEQ ID NO. 2 is identical to the Cla-I protein disclosed in Calvo and Vega (1993) J. Biol. Chem. 268:18929. ... The nucleotide sequence of a full length cDNA encoding the splice variant is set forth in SEQ ID NO. 3 and the amino acid sequence of

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the SR-BI splice variant protein encoded by this nucleotide sequence is set forth in SEQ ID NO. 4.

In addition, the '141 patent discloses that "[t]he SR-BI receptor (Scavenger Receptor-BI) is a scavenger receptor that mediates endocytosis of unmodified and modified lipoproteins, e.g., LDL, [and] acetylated LDL, ..."

We also note that Calvo is cited on the '141 patent as considered by the examiner. See page 2.

Claim 10 of the '141 patent is drawn to:

An isolated nucleic acid, comprising an allelic variant of a polymorphic region of an SR-BI gene, which allelic variant differs from the allelic variant set forth in SEQ ID NO. 1 or 3.

It appears that claim 11 on appeal and claim 10 of the '141 patent contain overlapping subject matter. Therefore, upon return of this application, the examiner should step back and consider the '141 patent and determine its effect if any on the claims on appeal.

We note that the examiner may issue a rejection if appropriate under these circumstances. However, if the ground of rejection is also applicable to the corresponding claims in the patent, any letter including the rejection must have the approval of the Group Director. Compare Manual of Patent Examining Procedure (MPEP) § 2307.02 (7<sup>th</sup> ed., July 1998).

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3. CD36:

Claim 11 is drawn to an isolated nucleic acid molecule that hybridizes to SEQ ID Nos. 3 and 7 and encodes a protein that selectively binds to low density lipoprotein (LDL) and to modified lipoprotein (acetylated low density lipoprotein). According to page 12 of Appendix A of the Kreiger and Acton declaration, "CD36 binds acetylated LDL...." During the August 16, 2001 oral hearing, Monty Krieger confirmed that CD36 binds LDL and acetylated LDL.

Upon return of this application, the examiner should determine whether the nucleotide sequence of CD36 is available in the prior art and if so, whether any such prior art would be applicable against the claimed invention. To the extent that appellants would argue that the binding specificity of CD36 is distinct from the type BI scavenger receptor protein of the claimed invention, appellants should insure that the claimed invention clearly sets forth any such difference in binding specificity.

We state that we are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

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This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(D) (7<sup>th</sup> ed., rev. 1, February 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

## REMANDED

William F. Smith

Administrative Patent Judge

*Jon R. Scheiner*

Toni R. Scheiner

Administrative Patent Judge

Donald E. Adams

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BOARD OF PATENT

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